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10/706,255	11/12/2003	Ondrej Hendl	01068.US1	6868
25533	7590	10/29/2007	EXAMINER	
PHARMACIA & UPJOHN			TELLER, ROY R	
7000 Portage Road			ART UNIT	
KZO-300-104			PAPER NUMBER	
KALAMAZOO, MI 49001			1654	
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			10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,255	Applicant(s) HENDL ET AL.	
	Examiner Roy Teller	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12, 13, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 13, 16-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment, received 8/14/07.

Claims 1-17 are pending.

Claims 9-11 and 14-15 remain withdrawn.

Claims 1-8, 12-13 and 16-17 are under examination.

Response to Amendments/ Arguments

Applicant's arguments and amendments filed 8/14/07 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 12-13 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified liquid carrier, the liquid carrier being modified cotton seed oil that has been heated in the presence of air to increase its oxidation

products and yield a modified cottonseed oil, is not enabled for a modified liquid carrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same..."

The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C.

112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the

amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a composition comprising crystalline ceftiofur free acid (CCFA) as the bioactive pharmaceutical agent and modified cottonseed oil with saturated coconut oil as the modified liquid carriers. The composition is administered to a host, wherein the concentration of crystalline ceftiofur free acid ranges from about 50 mg/ml to about 250 mg/ml, and the composition is released to the host on a predictable sustained basis.

The state of the prior art and the predictability or lack thereof in the art: The prior art shows CCFA is useful for treating mammalian animals and humans to treat bacterial infections, see Dunn, USPN 5,721,359, column 7, lines 54-56. The prior art does not teach the use of the other embodiments outlined *supra*.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

The instant specification, page 16, example 1, recites the use of CCFA with modified cottonseed oil and saturated coconut oil. The instant specification fails to teach the use of the other embodiments outlined *supra*. The absence of working examples in the instant specification also fails to teach the other embodiments outlined *supra*. The instant specification does not provide guidance as to how the modification is to be done to the carrier, whether by structural or

Art Unit: 1654

functional modifications. The instant specification does not provide guidance for any and all modified carriers, only particular modifications of oils.

The breadth of the claims and the quantity of experimentation needed: The breadth of claims extends beyond the teaching in the instant specification. The quantity of experimentation needed to determine the viability of the claimed embodiments outlined *supra* is considered undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 12-13 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a modified liquid carrier". It is unclear if the modification is functional or structural and how the modification is defined.

All other claims depend directly or indirectly from the rejected claim and are therefore, also rejected under 35 USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 12-13 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn (USPN 5,721,359) in view of Foster (USPN 5,736,151).

The claimed invention is drawn to a composition comprising a bioactive pharmaceutical or specifically, crystalline ceftiofur free acid (CCFA) and one or more modified oils selected from corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil, or coconut oil as the liquid carrier. "Modified" is understood to mean a vehicle which, through physical, chemical or mechanical means, has been altered as compared to its natural (or "non-modified" in the case of synthetic liquid carriers) form such that the modified vehicle has an increased level of oxidation products. Modification is accomplished by heat or irradiation, among other means. The composition is administered to a host, wherein the concentration of crystalline ceftiofur free acid ranges from about 50 mg/ml to about 250 mg/ml, and the composition is released to the host on a predictable sustained basis.

Dunn teaches crystalline ceftiofur free acid as the cephalosporin antibiotic ceftiofur, see abstract and claim 1, column 17. Dunn discloses a composition with a pharmaceutically acceptable carrier, see claim 8, column 19. Dunn teaches that the composition is sustained-release, see claim 9, column 19. Dunn discloses the

Art Unit: 1654

composition as comprising from about 20 to 200 mg/ml of crystalline ceftiofur free acid, see claim 10, column 19. Dunn teaches the composition is nonaqueous, where the nonaqueous composition is an oil, selected from the group consisting of corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil and mixtures thereof, see claims 12, 13, and 14, column 19. Dunn teaches modifying the oil carrier by heat or irradiation in order to render it sterile, see column 8, lines 42-50.

Dunn teaches a pharmaceutical composition comprising crystalline ceftiofur free acid and a modified carrier as set forth *supra*. Dunn does not teach the use of coconut oil as in the claimed invention.

Foster teaches a composition where the drug is a cephalosporin, see claim 16, column 14. Foster discloses oil used in the composition as selected from the group consisting of canola oil, corn oil, cottonseed oil, olive oil, peanut oil, sesame oil, soybean oil, safflower oil, coconut oil, sunflower oil and palm oil, see claim 19, column 14. Foster teaches a volume of 90% heated cottonseed oil used in the preparation of the composition, see column 10, lines 26-28. Foster discloses the present invention provides for novel formulations, such as oil suspensions, see column 1, lines 6-7.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the coconut oil of Foster in the composition of Dunn as the equivalent of one or more of the vegetable oils disclosed by Dunn. While Foster does not specifically teach an amount of cottonseed oil with coconut oil in the composition, absent some

Art Unit: 1654

evidence to the contrary, the claimed ratios of oil constitute routine optimization of a known composition.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/706,255

Page 9

Art Unit: 1654

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1654

10/25/07

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A handwritten signature in black ink, appearing to be 'CR Tate', written in a cursive style.

CHRISTOPHER R. TATE
PRIMARY EXAMINER